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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,546	03/20/2001	Karl Kolter	51284	9100

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/811,546	KOLTER ET AL.	
	Examiner	Art Unit	
	ERIC E. SILVERMAN	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/09 has been entered.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-38, 40-54, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,837,032 to Ortega.

1. The new claims

The claims are quite similar to the claims that were previously presented and rejected as anticipated by Ortega. Note that claims 40-47 recite optional ingredients that need not be present. Nonetheless, Ortega teaches HPMC at col. 3, corresponding to instant claims 42-45. Oretega also teaches HPMC-phthalate in claim 10, corresponding to instant claim 47. Ortega also teaches polyvinylpyrrolidone, corresponding to instant claims 40-41.

2. Applicants' unpersuasive arguments

Applicants argue that Ortega requires HPMC-phthalate, which is allegedly forbidden by instant claim 35. This is unpersuasive for two reasons. First, while Ortega

does call for cellulose acetate phthalate in some embodiments, the reference also teaches embodiments where methyl cellulose acetate phthalate or esters of acrylic and methacrylic acid copolymers are used instead of cellulose acetate phthalate. See Ortega at claim 3. Second, the claim does not forbid component c) from including being stearic acid, cellulose acetate phthalate, or combinations thereof; the claim merely forbids component c) from *consisting of* stearic acid, cellulose acetate phthalate, or combinations thereof. Ortega's claim 10 comprises a lubricant, which includes stearic acid, magnesium stearate, and talc. Magnesium stearate is also a lipophilic additive. The lipophilic additive in Ortega includes magnesium stearate in addition to stearic acid,and cellulose acetate phthalate, and so does not consist of stearic acid, cellulose acetate phthalate, or combinations thereof.

With regard to claim 57, Applicants argue that Ortega does not teach products made by the claimed spray drying process. In response, when a claim to a product recites a process of making, the process is only a claim limitation when it imparts a property on the product that distinguishes over the prior art. Here, there is no reason to think that spray-dried material will be any different from material having identical compositions but made by the methods of Ortega.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-38, 40-54, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ortega.

Ortega has been discussed previously. As applicants correctly point out, Ortega notes that "polyvinylpyrrolidone, or cellulose derivatives such as hydroxypropyl methyl cellulose methyl cellulose, or sodium carboxy methyl cellulose" can all be used as water soluble polymers. Ortega does not, however, specify that two of these can be used in combination.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use a combination of two of the polymers specified by Ortega. Ortega indicates that all of the polymers listed are suitable individually as water soluble polymers in the Ortega dosage form. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. Cf. *In re Kerhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980); see also *Boston Scientific Scimed, Inc. v. Biogen Idec*, 554 F.3d 982, 89 U.S.P. Q.2d. 1704 (Fed. Cir. 2009) (combining aspects of two embodiments that are depicted next to each other in the specification is obvious).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kolter DE 197 09 663 in view of Ortega.

Note that Applicants remarks at 12 incorrectly state that the rejection is over Kolter US 6,066,334. The rejection is over the Kolter DE reference; the '334 patent is relied upon as a translation for Kolter DE.

1. The new claims

The new claim limitations were discussed above under the rejections over Ortega alone.

2. Applicants' unpersuasive arguments

Applicants argue that there is an unexpected result exemplified in Tables 4 and 6, which use hydroxypropylmethyl cellulose as component c). It is noted that an allegation of unexpected results can only support patentability of claims that are commensurate with the showing. Here, Applicants' admit that the showing is limited to HMPC. However, none of the claims limit component c) to HPMC. For example, in claim 35, component c) may be any water-soluble non-swelling polymer, or any water soluble swelling polymer, or any lipophilic additive. Applicants have not provided any rationale as to why the showing of HPMC, a single water-soluble swelling polymer, is commensurate with the entire scope of the claims. This is especially true for claim 35, which may include a lipophilic or non-swelling polymer instead of a swelling polymer. Even if the results in tables 4 and 6 were unexpected, they would be insufficient to support patentability of all that is claimed. Thus the examiner has not made any attempt to analyze whether or not the results referred to by the response are unexpected or not.

Specification

The amendment filed 5/21/2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: all of the material added on page 8 of the 5/21 response is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

In response to Applicants' comments, while Applicants' are correct that the specification need not disclose that which is already known, that is not germane to the issue of new matter. Applicants may not add matter not originally disclosed in the specification, even if the newly added matter was already known in the art.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

/Eric E Silverman/
Primary Examiner, Art Unit 1618